

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
2-ethylhexyl salicylate [see octyl salicylate]	=====	=====	=====	=====	=====	=====
2-ethylhexyl-4-phenylbenzophenone-2-carboxylic acid	topical analgesic	sunscreen	sunscreen	IISE	IISE	[64 FR 27682]
5-(3,3-dimethyl-2-norbornyliden)3-pentene-2-one [see bornelone]	=====	=====	=====	=====	=====	=====
8-hydroxyquinoline [see oxyquinoline]	=====	=====	=====	=====	=====	=====
acetaminophen						
internal analgesic	internal analgesic		analgesic	I	I	pending
internal analgesic	internal analgesic		antipyretic	I	I	pending
internal analgesic	internal analgesic		antirheumatic	IIE	not OTC	n/a
miscellaneous internal	menstrual/diuretic		analgesic	I	I	pending
miscellaneous internal	overindulgence in alcohol/food		overindulgence remedies (hangover)	I	I	pending
sedative	nighttime sleep aid		sleep aid	IIE	IIE	[54 FR 6826]
sedative	daytime sedative		sedative	IISE	IISE	310.519(a)
acetanilid [see acetanilide]	=====	=====	=====	=====	=====	=====

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
acetanilide						
	internal analgesic	internal analgesic	analgesic	IIS	IIS	pending
	internal analgesic	internal analgesic	antipyretic	IIS	IIS	pending
	internal analgesic	internal analgesic	antirheumatic	IISE	not OTC	n/a
acetic acid						
=====	otic		swimmer's ear prevention	n/a	IIIIE	310.545(15)(i)
contraceptive/vaginal	vaginal		alters vaginal pH	IIIIE	withdraw	n/a
miscellaneous external	wart remover		wart remover	IIISE	IIISE	[55 FR 33254]
acetic acid, glacial						
miscellaneous external	wart remover		wart remover	IIIIE	IIISE	[55 FR 33254]
miscellaneous external	corn/callus remover		corn/callus remover	IIIIE	IIISE	[55 FR 33261]
acetone						
miscellaneous external	external analgesic		astringent	IISE	n/a	pending
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(18)(ii)
acidulated phosphate fluoride (sod fluoride/sod phos /phos acid)						
dental	anticaries		anticavity dental rinse	I	I	355.10(a)(2)(ii)
acidulated phosphate fluoride (sodium fluoride/hydrogen fluoride)						
dental	anticaries		anticavity dental rinse	IIS	IIS	355.10(a)(2)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
acidulated phosphate fluoride (sodium fluoride/sodium phos dibasic/ phos acid)						
dental	anticaries		anticavity dental rinse	I	I	355.10(a)(3)(ii)
agar						
laxative	laxative		bulk laxative	III	III	310.545(12)(i)
alanine						
miscellaneous internal	benign prostatic hypertrophy		benign prostatic hypertrophy	II	II	310.532(a)
alcloxa						
antimicrobial II	acne		acne	II	II	310.545(1)
antimicrobial II	antifungal		antifungal	III	III	310.545(22)(ii)
hemorrhoidal	anorectal		keratolytic (external)	I	I	346.20(a)
hemorrhoidal	anorectal		keratolytic (intrarectal)	I	I	346.20(a)
alcohol						
miscellaneous external	alcohols (topical)		antiseptic	I	defer	n/a
miscellaneous external	mercury		first aid antiseptic	n/a	I	pending
miscellaneous external	external analgesic		astringent	II	n/a	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	defer	n/a
miscellaneous external	external analgesic		insect bite/sting	II	II	310.545(a)(10)(vi)
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	II	310.545(a)(10)(vii)
miscellaneous external	skin protectant		astringent	II	II	310.545(a)(18)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(18)(v)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)
	miscellaneous external	skin protectant	fever blister (topical)	IISE	IISE	pending
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
	miscellaneous internal	menstrual/diuretic	analgesic adjuvant	n/a	IISE	310.545(a)(24)(i)
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
	oral cavity	oral health care	antimicrobial	IIIIE	IIISE	pending
alcohol, 14 percent [see alcohol]						
	====	====	====	====	====	====
alcohol, ethoxylated alkyl						
	====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(A)
aldioxa						
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(ii)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	IIISE	pending
alfalfa						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
alfalfa leaves						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
alginic acid						
antacid	antacid		antacid	IIIIE	IIIE	[39 FR 19873]
miscellaneous internal	weight control		anorectic	IIIIE	IISE	310.545(a)(20)
alkaloids of sabadilla [see sabadilla alkaloids]						
=====	=====		=====	=====	=====	=====
alkyl arylsulfonate						
contraceptive/vaginal	vaginal		lowers surface tension mucolytic effects	IIIIE	withdraw	n/a
alkyl dimethyl amine oxide and alkyl dimethyl glycine						
=====	gingivitis/plaque		antiplaque/gingivitis	n/a	IISE	pending
alkyl isoquinolinium bromide						
antimicrobial II	acne		acne	IIIE	IIIE	310.545(a)(1)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		IIIIE	IIIE	310.545(a)(7)
alkyldimethyl benzylammonium chloride [see benzalkonium chloride]						
=====	=====		=====	=====	=====	=====
allantoin						
contraceptive/vaginal	vaginal		minor irritations	IIIIE	withdraw	n/a
dental	oral mucosal injury		wound healing agent	IIIIE	IIIE	310.534(a)

OTC Ingredient List
Updated May 2005

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis/psoriasis	IIIIE	IIIIE	310.545(a)(7)
miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending
miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	pending
miscellaneous external	hair growth/loss	hair grower	IISE	n/a	310.527(a)
miscellaneous external	skin protectant	diaper rash	defer	I	pending
miscellaneous external	skin protectant	fever blister (topical)	defer	I	pending
miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	pending
miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
topical analgesic	skin protectant	skin protectant	I	I	347.10(a)
topical analgesic	skin protectant	wound healing agent	IIIIE	IIIIE	310.545(a)(18)(i)(A)
allantoin (with aminobenzoic acid)					
topical analgesic	sunscreen	sunscreen	IIIIE	IIIIE	[64 FR 27682]
allyl isothiocyanate					
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IISE	IISE	310.545(a)(6)(ii)(A)
miscellaneous external	external analgesic	fever blister (topical)	defer	IISE	310.545(a)(10)(v)
topical analgesic	external analgesic	counterirritant	I	I	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
almadrate sulfate						
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIIIE	n/a	310.545(a)(8)(ii)
aloe						
=====	skin protectant		diaper rash	n/a	withdraw	n/a
contraceptive/vaginal	vaginal		minor irritations	IIIIE	withdraw	n/a
laxative	laxative		stimulant laxative	I	I/IIS	310.545(a)(12)(iv)(C)
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
aloe extract						
=====	laxative		stimulant laxative	n/a	n/a	310.545(a)(12)(iv)(C)
aloe flower extract						
=====	laxative		stimulant laxative	n/a	n/a	310.545(a)(12)(iv)(C)
aloe vera [see aloe]						
=====	gingivitis/plaque		antiplaque/gingivitis	n/a	IIIIE	pending
aloe vera stabilized [see aloe]						
=====	=====		=====	=====	=====	=====
aloes [see aloe]						
=====	=====		=====	=====	=====	=====
aloin						
laxative	laxative		stimulant laxative	IISE	IISE	310.545(a)(12)(iv)(A)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
alum (powdered alum) [see alum, ammonium/alum, potassium]	====	====	====	====	====	====
alum [see alum, ammonium/alum, potassium]	====	====	====	====	====	====
alum ammonium [see alum, ammonium]	====	====	====	====	====	====
alum, ammonium						
contraceptive/vaginal	vaginal	astringent		IIIIE	withdraw	n/a
miscellaneous external	external analgesic	astringent		IISE	n/a	pending
miscellaneous external	skin protectant	astringent		IISE	IISE	310.545(a)(18)(ii)
oral cavity	astringent	astringent		I	defer	n/a
oral cavity	oral health care	astringent		I	I	pending
alum, potassium						
antimicrobial II	antifungal	antifungal		IIIIE	IIIIE	310.545(a)(22)(ii)
antiperspirant	antiperspirant	antiperspirant		IIISE	IIISE	310.545(a)(4)
contraceptive/vaginal	vaginal	astringent		IIIIE	withdraw	n/a
miscellaneous external	external analgesic	astringent		IISE	n/a	pending
miscellaneous external	skin protectant	astringent		IISE	IISE	310.545(18)(ii)
oral cavity	oral health care	astringent		I	I	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum acetate						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		astringent	I	I	347.12(a)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		astringent	I	I	347.10(a)
miscellaneous external	skin protectant		diaper rash	defer	IISE	pending
aluminum aspirin [see aspirin, aluminum]	====	====	====	====	====	====
aluminum bromohydrate						
antiperspirant	antiperspirant		antiperspirant	IISE	IISE	310.545(a)(4)
aluminum carbonate (gel) [see aluminum hydroxide]	====	====	====	====	====	====
aluminum carbonate gel (basic)						
antacid	antacid		antacid	I	I	331.11(a)(1)
aluminum carbonate gel [see basic aluminum carbonate gel]	====	====	====	====	====	====
aluminum chlorhydroxy complex						
miscellaneous external	external analgesic		astringent	IISE	n/a	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
aluminum chloride (aerosol) (15% or less aqueous solution)						
antiperspirant	antiperspirant	antiperspirant		IIIS	IIIS	310.545(a)(4)
aluminum chloride (alcoholic solutions)						
antiperspirant	antiperspirant	antiperspirant		IIS	IIS	310.545(a) (4)
aluminum chloride (nonaerosol) (15% or less aqueous solution)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(a)
aluminum chloride hexahydrate						
miscellaneous external	external analgesic	astringent		n/a	IIIIE	pending
aluminum chlorohydrate (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIIS	I	350.10(b)
aluminum chlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(b)
aluminum chlorhydrrex						
antimicrobial II	acne	acne		IIE	IIE	310.545(a)(1)
aluminum chlorhydrrex polyethylene glycol (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIIS	I	350.10(c)
aluminum chlorhydrrex polyethylene glycol (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(c)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum chlorohydrex polyethylene glycol complex [see name with “complex”]	=====	=====	=====	=====	=====	=====
aluminum chlorohydrex polyplene glycol (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIIS	I	350.10(d)
aluminum chlorohydrex polyplene glycol (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(d)
aluminum dichlorohydrate						
antiperspirant	antiperspirant	antiperspirant		IIIS	I	350.10(e)
aluminum dichlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(e)
aluminum dichlorohydrex polyethylene glycol (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIIS	I	350.10(f)
aluminum dichlorohydrex polyethylene glycol (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(f)
aluminum dichlorohydrex polyethylene glycol complex [see name with “complex”]	=====	=====	=====	=====	=====	=====
aluminum dichlorohydrex propylene glycol (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIIS	I	350.10(g)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum dichlorohydrex propylene glycol (nonaerosol)						
antiperspirant	antiperspirant		antiperspirant	I	I	350.10(g)
aluminum dichlorohydrex propylene glycol complex [see name with "complex"]	=====	=====	=====	=====	=====	=====
aluminum dihydroxy allantoinate [see aldioxa]	=====	=====	=====	=====	=====	=====
aluminum hydroxide						
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
antimicrobial II	antifungal		acne	IIE	IIE	310.545(a)(1)
antacid	antacid		antacid	I	I	331.11(a)(2)
laxative	antidiarrheal		antidiarrheal	IIIIE	IIIIE	310.545(a)(3)(i)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	IIISE	310.545(a)(18)(iii)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIIIE	n/a	310.545(a)(8)(ii)
miscellaneous internal	overindulgence in alcohol/food		overindulgence remedies (hangover)	I	I	pending
topical analgesic	skin protectant		skin protectant	I	I	347.10(b)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum hydroxide (gel) [see aluminum hydroxide gel]	=====	=====	=====	=====	=====	=====
aluminum hydroxide gel						
	=====	skin protectant	poison ivy/oak/sumac	n/a	I	347.10(b)
hemorrhoidal		anorectal	protectant (intrarectal)	I	I	346.14(1)
hemorrhoidal		anorectal	protectant (external)	I	I	346.14(1)
internal analgesic		internal analgesic	corrective	I	n/a	n/a
miscellaneous internal		overindulgence in alcohol/food	overindulgence remedies (hangover)	I	I	pending
topical analgesic		skin protectant	skin protectant	I	I	347.10(b)
aluminum hydroxide sucrose powder hydrated						
antacid		antacid	antacid	I	I	331.11(a)(2)
aluminum hydroxide-hexitol, stabilized polymer						
antacid		antacid	antacid	I	I	331.11(a)(2)
aluminum hydroxide-magnesium carbonate, co-dried gel						
antacid		antacid	antacid	I	I	331.11(a)(2)
aluminum hydroxide-magnesium trisilicate, co-dried gel						
antacid		antacid	antacid	I	I	331.11(a)(2)
aluminum phosphate (gel) [see aluminum phosphate gel]	=====	=====	=====	=====	=====	=====

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum phosphate gel						
antacid	antacid		antacid	I	I	331.11(i)(1)
miscellaneous internal	hypophosphatemia/hyperphosphatemia	hypophosphatemia		IIS	IIS	310.541(a)
aluminum phosphate gel (when used as part of antacid combination)						
antacid	antacid		antacid	I	I	331.11(a)(4)
aluminum sesquichlorohydrate (aerosol)						
antiperspirant	antiperspirant		antiperspirant	IIIS	I	350.10(h)
aluminum sesquichlorohydrate (nonaerosol)						
antiperspirant	antiperspirant		antiperspirant	I	I	350.10(h)
aluminum sesquichlorohydrate propylene glycol (nonaerosol)						
antiperspirant	antiperspirant		antiperspirant	I	I	350.10(j)
aluminum sesquichlorohydrate propylene glycol complex [see name without "complex"]	====	====	====	====	====	====
aluminum sesquichlorohydrate poylethylene glycol (aerosol)						
antiperspirant	antiperspirant		antiperspirant	IIIS	I	350.10(i)
aluminum sesquichlorohydrate poylethylene glycol (nonaerosol)						
antiperspirant	antiperspirant		antiperspirant	I	I	350.10(i)
aluminum sulfate						
antimicrobial II	antifungal		antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	antiperspirant	antiperspirant	antiperspirant	IIISE	IIISE	310.545(a)(4)
miscellaneous external	external analgesic		astringent	IIIIE	n/a	pending
miscellaneous external	skin protectant		astringent	IIIIE	I	347.12(b)
aluminum sulfate, buffered (aerosol)						
	antiperspirant	antiperspirant	antiperspirant	IIIS	IIIS	310.545(a)(4)
aluminum sulfate, buffered (nonaerosol)						
	antiperspirant	antiperspirant	antiperspirant	I	I	310.545(a)(4)
aluminum zirconium octachlorohydrate (aerosol)						
	antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)
aluminum zirconium octachlorohydrate (nonaerosol)						
	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(k)
aluminum zirconium octachlorohydrex glycine (aerosol)						
	antiperspirant	antiperspirant	antiperspirant	IIS	IIS	310.502(a)(2)
aluminum zirconium octachlorohydrex glycine (nonaerosol)						
	antiperspirant	antiperspirant	antiperspirant	I	I	350.10(1)
aluminum zirconium octachlorohydrex glycine complex [see name without "complex"]						
	=====	=====	=====	=====	=====	=====
aluminum zirconium pentachlorohydrate (aerosol)						
	antiperspirant	antiperspirant	antiperspirant	IIS	IIS	350.10(m)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum zirconium pentachlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(m)
aluminum zirconium pentachlorohydrex glycine (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIS	IIS	310.502(a)(2)
aluminum zirconium pentachlorohydrex glycine (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(m)
aluminum zirconium pentachlorohydrex glycine complex [see name without “complex”]						
=====	=====	=====		=====	=====	=====
aluminum zirconium tetrachlorohydrate (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIS	IIS	310.502(a)(2)
aluminum zirconium tetrachlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(o)
aluminum zirconium tetrachlorohydrex glycine (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIS	IIS	310.502(a)(2)
aluminum zirconium tetrachlorohydrex glycine (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(p)
aluminum zirconium tetrachlorohydrex glycine complex [see name without “complex”]						
=====	=====	=====		=====	=====	=====

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aluminum zirconium trichlorohydrate (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIS	IIS	310.502(a)(2)
aluminum zirconium trichlorohydrate (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(q)
aluminum zirconium trichlorohydrex glycine (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIS	IIS	310.502(a)(2)
aluminum zirconium trichlorohydrex glycine (nonaerosol)						
antiperspirant	antiperspirant	antiperspirant		I	I	350.10(r)
aluminum zirconium trichlorohydrex glycine complex [see name without “complex”]						
=====	=====	=====		=====	=====	=====
aluminum sesquichlorohydrate propylene glycol (aerosol)						
antiperspirant	antiperspirant	antiperspirant		IIIS	I	350.10(r)
aminacrine hydrochloride						
miscellaneous external	boil treatment	boil treatment		IISE	IISE	310.531(a)
amino acids						
miscellaneous external	hair growth/loss	hair grower		IISE	IIE	310.527(a)
aminoacetic acid [see glycine]						
=====	=====	=====		=====	=====	=====

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
aminoacridine hydrochloride [see aminacrine hydrochloride]						
=====	=====	=====	=====	=====	=====	=====
aminobenzoic acid						
internal analgesic	internal analgesic		analgesic adjuvant	IISE	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antipyretic adjuvant	IISE	IISE	310.545(a) (23)(i)
internal analgesic	internal analgesic		antirheumatic adjuvant	IISE	n/a	310.545(a) (23)(i)
miscellaneous external	hair growth/loss		hair grower	n/a	IIE	310.527(a)
aminobenzoic acid (PABA)						
topical analgesic	sunscreen		sunscreen	I	I	352.10(b)
aminophylline						
cough/cold	cough/cold (bronchodilator)		bronchodilator	I	IIS	310.545(a)(6)(iv)(A)
ammonia						
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	pending
ammonia solution, strong						
miscellaneous external	external analgesic		insect bite/sting	IISE	IISE	310.545(a)(18)(v)(A)
miscellaneous external	skin protectant		insect bite/sting	IISE	IISE	310.545(a)(18)(v)
topical analgesic	external analgesic		counterirritant	I	I	pending
topical analgesic	external analgesic		fever blister (topical)	n/a	IISE	310.545(a)(10)(v)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
ammonium alum [see alum, ammonium]	=====	=====	=====	=====	=====	=====
ammonium bromide						
sedative		daytime sedative	sedative	IISE	IISE	310.519(a)
sedative		nighttime sleep aid	sleep aid	IISE	IISE	[54 FR 6826]
ammonium carbonate						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	pending
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	pending
ammonium chloride						
cough/cold	cough/cold (expectorant)		expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
miscellaneous internal	menstrual/diuretic		diuretic	I	I	pending
oral cavity	oral health care		expectorant	IIIIE	IIIIE	310.545(a)(6)(iii)
sedative	stimulant		stimulant	IIE	IIE	[39 FR 6104]
ammonium hydroxide						
miscellaneous external	external analgesic		insect bite/sting	IIIIE	IIIIE	310.545(a)(18)(v)(A)
miscellaneous external	skin protectant		insect bite/sting	IIIIE	IIISE	310.545(a)(18)(v)(A)
amyl dimethyl-p-aminobenzoate [see padimate A]	=====	=====	=====	=====	=====	=====

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
amyl para-dimethylaminobenzoate [see padimate A]	=====	=====	=====	=====	=====	=====
amylase	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(8)(ii)
amyltricresols, secondary	antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)
	oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending
amylum [see starch]	=====	=====	=====	=====	=====	=====
amyltricresol, secondary [see amyltricresols, secondary]	=====	=====	=====	=====	=====	=====
anion and cation exchange resins buffered	miscellaneous external	external analgesic	poison ivy/oak/sumac	IIIIE	IIIIE	pending
	miscellaneous external	skin protectant	poison ivy/oak/sumac	IIIIE	IIIIE	310.545(a)(10)(vii)(A)
anise	miscellaneous internal	aphrodisiac	aphrodisiac	n/a	n/a	310.528(a)
anise oil	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
anise seed						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
antimony potassium tartrate						
cough/cold	cough/cold (expectorant)		expectorant	IISE	IISE	310.545(a)(6)(iii)
antipyrine						
internal analgesic	internal analgesic		analgesic	IIISE	IIISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antipyretic	IIISE	IIISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antirheumatic	IIISE	not OTC	310.545(a)(23)(i)
oral cavity	oral health care		analgesic/anesthetic	IISE	IISE	310.545(a)(14)
ophthalmic	ophthalmic		analgesic/anesthetic	IIS	IIS	310.545(a)(21)(i)
topical analgesic	otic		analgesic/anesthetic	IISE	IISE	[51 FR 28660]
aqua ammonia [see ammonium solution, strong]						
=====	=====		=====	=====	=====	=====
aqueous coconut oil soap [see coconut oil soap, aqueous]						
=====	=====		=====	=====	=====	=====
arginine						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
aromatic oils						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
	miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending
aromatic powder						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
aromatics						
	miscellaneous external	external analgesic	astringent	IISE	n/a	pending
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
asafetida						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
asclepias tuberosa						
	miscellaneous internal	menstrual/diuretic	dysmenorrhea	IISE	IISE	310.545(a)(24)(i)
ascorbic acid						
	miscellaneous external	hair growth/loss	hair grower	IIIIE	IIIIE	310.527(a)
	miscellaneous external	wart remover	wart remover	IIIIE	IIIIE	[55 FR 33254]
	miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
asparagus						
	miscellaneous internal	menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
aspergillus oryzae enzymes (except lactase enzyme from aspergillus oryzae)						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
aspirin						
=====		external analgesic	fever blister (topical)	n/a	IIIIE	310.545(a)(10)(v)
=====		external analgesic	poison ivy/oak/sumac	n/a	IIIIE	310.545(a)(10)(vii)
internal analgesic	internal analgesic	analgesic		I	I	pending
internal analgesic	internal analgesic	antipyretic		I	I	pending
internal analgesic	internal analgesic	antirheumatic		I	not OTC	n/a
miscellaneous internal	menstrual/diuretic	analgesic		I	I	pending
miscellaneous internal	overindulgence in alcohol/food	overindulgence remedies (hangover)		I	I	pending
oral cavity	oral health care	analgesic/anesthetic		I	IIIIE	pending
sedative	daytime sedative	sedative		IIE	IISE	310.519(a)
sedative	nighttime sleep aid	sleep aid		IIE	IIE	[54 FR 6826]
topical analgesic	external analgesic	analgesic/anesthetic		IIIIE	IIIIE	310.545(a)(10)(i)
aspirin, aluminum						
internal analgesic	internal analgesic	analgesic		n/a	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic	antipyretic		IIIIE	IIIIE	310.545(a)(23)(i)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	internal analgesic	internal analgesic	antirheumatic	IIIIE	not OTC	310.545(a)(23)(i)
aspirin, calcium						
	internal analgesic	internal analgesic	analgesic	I	I	pending
	internal analgesic	internal analgesic	antipyretic	I	I	pending
	internal analgesic	internal analgesic	antirheumatic	I	not OTC	n/a
	miscellaneous internal	menstrual/diuretic	analgesic	I	I	pending
atropine						
====		menstrual/diuretic	menstrual	n/a	n/a	310.545(a)(24)(ii)
====		internal analgesic	analgesic	n/a	n/a	310.545(a)(23)(ii)
hemorrhoidal	anorectal		anticholinergic (external)	IISE	IISE	310.545(a)(26)(i)
hemorrhoidal	anorectal		anticholinergic (intrarectal)	IISE	IISE	310.545(a)(26)(i)
atropine sulfate						
cough/cold		cough/cold (anticholinergic)	anticholinergic	IIIIE	IIIIE	310.533(a)
laxative		antidiarrheal	antidiarrheal	IIISE	IIISE	310.545(a)(3)(i)
attapulgite, activated						
laxative		antidiarrheal	antidiarrheal	IIIIE	I	310.545(a)(3)(ii)
avobenzone						
====	n/a		sunscreen	n/a	1	352.10(a)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
bacillus acidophilus						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
bacitracin						
antimicrobial II	antibiotic		first aid antibiotic	n/a	I	333.110(a)
antimicrobial II	antibiotic		skin wound antibiotic	IIIIE	defer	n/a
bacitracin zinc						
antimicrobial II	antibiotic		first aid antibiotic	n/a	I	333.110(b)
balsam peru [see peruvian balsam]						
=====	=====		=====	=====	=====	=====
balsam peru oil [see peruvian balsam oil]						
=====	=====		=====	=====	=====	=====
barosma						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
basic aluminum carbonate gel						
miscellaneous internal	hypophosphatemia/hyperphosphatemia	hyperphosphatemia		IIS	IIS	310.541(a)
basic fuchsin						
antimicrobial II	antifungal		antifungal	IIISE	IIISE	310.545(a)(22)(ii)
bean						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
bearberry						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
bearberry (extract of uva ursi)						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
bearberry fluidextract (extract of bearberry)						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
beeswax						
=====	insect bite/sting		insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)
=====	poison ivy/oak/sumac		poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	pending
miscellaneous external	skin protectant		diaper rash	defer	n/a	310.545(a)(18)(i)(B)
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	pending
belladonna alkaloids						
cough/cold	cough/cold (bronchodilator)		bronchodilator (inhalation)	IISE	IISE	310.545(a)(6)(iv)(A)
cough/cold	cough/cold (anticholinergic)		anticholinergic	IIIIE	IIIIE	310.533(a)
miscellaneous external	corn/callus remover		corn/callus remover	IISE	IISE	[55 FR 33261]

OTC Ingredient List
Updated May 2005

Ingredient		Drug Category	ANPR	PR	FR
Review Panel	Report				
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
belladonna alkaloids (inhalation) atropa belladonna/datura stramonium					
cough/cold	cough/cold (anticholinergic)	anticholinergic	IISE	IISE	310.533(a)
belladonna extract					
hemorrhoidal	anorectal	anticholinergic (intrarectal)	IISE	IISE	310.545(a)(26)(i)
hemorrhoidal	anorectal	anticholinergic (external)	IISE	IISE	310.545(a)(26)(i)
belladonna leaves, powdered extract					
miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
benzalkonium chloride					
antimicrobial I	antimicrobial	antimicrobial soap	n/a	IISE	pending
antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending
antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending
antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending
antimicrobial I	antimicrobial	skin wound cleanser	I	I	pending
antimicrobial I	antimicrobial	skin wound protectant	IIISE	IIISE	pending
antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw	n/a
miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash	defer	IISE	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	IIIIE	IIIIE	310.545(a)(7)
	miscellaneous external	external analgesic	astringent	IIISE	n/a	pending
	miscellaneous external	external analgesic	fever blister (topical)	defer	n/a	pending
	miscellaneous external	external analgesic	insect bite/sting	IIISE	IIISE	310.545(a)(10)(vi)
	miscellaneous external	skin protectant	astringent	IIISE	IIISE	310.545(a)(18)(ii)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
	miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending
	miscellaneous external	skin protectant	insect bite/sting	IIISE	IIISE	310.545(a)(18)(v)(A)
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
benzethonium chloride						
	antimicrobial I	antimicrobial	first aid antiseptic	n/a	I	pending
	antimicrobial I	antimicrobial	surgical hand scrub	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	skin antiseptic	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	skin wound cleanser	I	I	pending
	antimicrobial I	antimicrobial	skin wound protectant	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	antimicrobial soap	n/a	IIISE	pending
	antimicrobial I	antimicrobial	preoperative skin prep	IIISE	IIISE	pending
	antimicrobial I	antimicrobial	health care personnel handwash	IIIIE	IIIIE	pending
	antimicrobial II	antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(ii)

OTC Ingredient List
Updated May 2005

Ingredient			Drug Category	ANPR	PR	FR
Review Panel	Report					
miscellaneous external	antifungal		diaper rash	defer	I ^a S ^b E	310.545(a)(22)(i)
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/cradle cap		III ^c E	III ^c E	310.545(a)(7)
miscellaneous external	external analgesic	astringent		I ^a S ^b E	n/a	310.545(a)(18)(ii)
miscellaneous external	external analgesic	poison ivy/oak/sumac		defer	I ^a S ^b E	310.545(a)(10)(vii)
miscellaneous external	skin protectant	astringent		I ^a S ^b E	I ^a S ^b E	310.545(a)(18)(ii)
miscellaneous external	skin protectant	diaper rash		defer	n/a	pending
miscellaneous external	skin protectant	poison ivy/oak/sumac		defer	I ^a S ^b E	310.545(a)(10)(vii)(A)
miscellaneous external	external analgesic	diaper rash		defer	n/a	310.545(a)(22)(i)
miscellaneous external	external analgesic	diaper rash		defer	n/a	310.545(a)(10)(iv)
oral cavity	oral health care	antimicrobial		I ^a S ^b E	I ^a S ^b E	pending
benzocaine						
antimicrobial II	acne	acne		I ^a S ^b E	I ^a S ^b E	310.545(a)(1)
contraceptive/vaginal	vaginal	minor irritations		III ^c E	withdraw	n/a
dental	relief of oral discomfort	oral mucosal analgesic		I	I	pending
dental	relief of oral discomfort	toothache relief		III ^c E	III ^c E	pending
hemorrhoidal	anorectal	anesthetic (intrarectal)		III ^c E	III ^c E	[55 FR 1779]
hemorrhoidal	anorectal	anesthetic (external)		I	I	346.10(a)
miscellaneous external	antifungal	diaper rash		defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial	diaper rash		defer	n/a	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	boil treatment	boil treatment	IISE	IIISE	310.531(a)
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis	IIE	IIE	[56 FR 63567]
	miscellaneous external	external analgesic	astringent	IISE	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	IISE	310.545(a)(10)(iv)
	miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
	miscellaneous external	external analgesic	insect bite/sting	n/a	IIIIE	pending
	miscellaneous external	male genital desensitizer	male genital desensitizer	I	I	348.10(a)(1)
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending
	miscellaneous external	external analgesic	poison/ivy/oak/sumac	defer	IIIIE	IIISE (0.5-1.25%)
	miscellaneous external	pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
	miscellaneous external	skin protectant	fever blister (topical)	defer	DEF	pending
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	n/a	310.545(a)(10)(vii)
	miscellaneous external	wart remover	wart remover	IISE	IISE	[55 FR 33254]
	miscellaneous internal	weight control	anorectic	I	IISE	pending
oral cavity		oral health care	analgesic/anesthetic	I	I	pending
topical analgesic		external analgesic	analgesic/anesthetic	I	I	pending
topical analgesic		otic	analgesic/anesthetic	IISE	IISE	[51 FR 28660]

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	topical analgesic	external analgesic	poison ivy/oak/sumac	IIIIE	n/a	310.545(a)(10)(vii)
benzoic acid						
antimicrobial II	acne	acne		IIE	IIE	310.545(a)(1)
antimicrobial II	antifungal	antifungal		IIIIE	IIIE	310.545(a)(22)(ii)
miscellaneous external	external analgesic	astringent		IIISE	n/a	n/a
miscellaneous external	hair growth/loss	hair grower		IIE	IIE	310.527(a)
miscellaneous external	skin protectant	astringent		IIISE	IIISE	310.545(a)(18)(ii)
oral cavity	oral health care	antimicrobial		IIIIE	IIIE	pending
benzoin tincture, compound						
cough/cold	cough/cold (expectorant)	expectorant (topical/inhalant)		IIIIE	IIIE	310.545(a)(6)(iii)
dental	relief of oral discomfort	oral mucosal protectant		I	I	pending
benzoin, tincture						
cough/cold	cough/cold (expectorant)	expectorant		n/a	n/a	310.545(a)(6)(iii)
benzonatate						
cough/cold	cough/cold (antitussive)	antitussive		n/a	I	310.533(a)
benzoxiquine						
antimicrobial II	antifungal	antifungal		IIISE	IIISE	310.545(a)(22)(ii)
benzoyl peroxide						
antimicrobial II	acne	acne		I	I	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
benzyl alcohol						
	dental	relief of oral discomfort	toothache relief	IIISE	IIISE	pending
	dental	relief of oral discomfort	oral mucosal analgesic	IIISE	I	pending
	hemorrhoidal	anorectal	anesthetic (external)	IIIIE	I	346.10(b)
	hemorrhoidal	anorectal	anesthetic (intrarectal)	IIIIE	IIIIE	[55 FR 1779]
	miscellaneous external	alcohols (topical)	antiseptic	IIE	defer	n/a
	miscellaneous external	external analgesic	fever blister (topical)	defer	I	pending
	miscellaneous external	male genital desensitizer	male genital desensitizer	IIISE	IIISE	310.545(a)(10)(iii)
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending
	miscellaneous external	pediculicide	pediculicide	IIISE	IIISE	310.545(a)(25)(i)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIISE	310.545(a)(10)(vii)(A)
	oral cavity	oral health care	analgesic/anesthetic	I	I	pending
	topical analgesic	external analgesic	analgesic/anesthetic	I	I	pending
benzyl benzoate						
	miscellaneous external	pediculicide	pediculicide	IIISE	IIISE	310.545(a)(25)(i)
betaine hydrochloride						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
	miscellaneous internal	stomach acidifier	stomach acidifier	IIE	IIIE	310.540(a)

OTC Ingredient List
Updated May 2005

Ingredient Review Panel	Report	Drug Category	ANPR	PR	FR
bicarbonate					
antacid	antacid	antacid	n/a	n/a	331.11(b)
			=====	=====	=====
bicarbonate of soda [see sodium bicarbonate]					
			=====	=====	=====
bile salts/acids					
laxative	laxative	stimulant laxative	IIISE	IIISE	310.545(a)(12)(iv)(A)
biotin					
miscellaneous external	hair growth/loss	hair grower	n/a	IISE	310.527(a)
miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
bisacodyl					
laxative	laxative	stimulant laxative	I	I/IIIS	pending
bismuth aluminate					
antacid	antacid	antacid	I	I	331.11(c)(1)
bismuth carbonate					
antacid	antacid	antacid	I	I	331.11(c)(2)
bismuth oxide					
hemorrhoidal	anorectal	protectant (external)	IIIIE	IIIIE	310.545(a)(26)(viii)
hemorrhoidal	anorectal	protectant (intrarectal)	IIIIE	IIIIE	310.545(a)(26)(viii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
bismuth sodium tartrate						
miscellaneous external	external analgesic		fever blister (topical)	defer	IIISE	310.545(a)(10)(v)
miscellaneous external	skin protectant		fever blister (topical)	defer	defer	pending
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IISE	IISE	310.545(a)(8)(i)
bismuth subcarbonate						
antacid	antacid		antacid	I	I	331.11(c)(3)
hemorrhoidal	anorectal		protectant (intrarectal)	IIIIE	IIIIE	310.545(a)(26)(viii)
hemorrhoidal	anorectal		protectant (external)	IIIIE	IIIIE	310.545(a)(26)(viii)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
bismuth subgallate						
antacid	antacid		antacid	I	I	331.11(c)(4)
hemorrhoidal	anorectal		protectant (external)	IIIIE	IIIIE	310.545(a)(26)(viii)
hemorrhoidal	anorectal		protectant (intrarectal)	IIIIE	IIIIE	310.545(a)(26)(viii)
miscellaneous internal	deodorants for internal use		internal deodorant	IIIIE	I	357.810(a)
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
bismuth subnitrate						
	====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)
	====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)
	====	skin protectant	fever blister (topical)	n/a	IISE	310.545(a)(10)(iv)
	====	skin protectant	poison ivy/oak/sumac	n/a	IISE	310.545(a)(10)(vii)(A)
	antacid	antacid	antacid	I	I	331.11(c)(5)
	hemorrhoidal	anorectal	protectant (external)	IIS	IIS	310.545(a)(26)(viii)
	laxative	antidiarrheal	antidiarrheal	IISE	IISE	pending
	miscellaneous external	anorectal	protectant (intrarectal)	IIS	IIS	310.545(a)(26)(viii)
	miscellaneous external	antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	skin protectant	diaper rash	defer	IISE	pending
	topical analgesic	skin protectant	skin protectant	IISE	IISE	pending
bismuth subsalicylate						
	laxative	antidiarrheal	antidiarrheal	IIIIE	IIIIE	335.10(a)
	laxative	antiemetic	antiemetic	IIIIE	IIIIE	defer (overindulgence)
	miscellaneous internal	overindulgence in alcohol/food	upset stomach	I	I	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
bithionol						
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external	skin protectant		poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vi)(A)
black radish powder						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
blessed thistle (<i>cnicus benedictus</i>)						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
miscellaneous internal	menstrual/diuretic		menstrual	n/a	IISE	310.545(a)(24)(i)
bone marrow, red						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
borax [see sodium borate]						
=====	=====	=====	=====	=====	=====	=====
boric acid						
=====	insect bite/sting		insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)
=====	poison ivy/oak/sumac		poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)
=====	skin protectant		fever blister (topical)	n/a	IISE	310.545(a)(18)(iv)
=====	skin protectant		poison ivy/oak/sumac	n/a	IISE	310.545(a)(10)(vii)(A)
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
antimicrobial II	antifungal		antifungal	IIIIE	IIIIE	310.545(a)(22)(ii)

OTC Ingredient List
Updated May 2005

Ingredient			Drug Category	ANPR	PR	FR
Review Panel	Report					
contraceptive/vaginal	vaginal		astringent	IIISE	withdraw	n/a
contraceptive/vaginal	vaginal		alters vaginal pH	IIISE	withdraw	n/a
contraceptive/vaginal	vaginal		lowers surface tension mucolytic effects	IIISE	withdraw	n/a
contraceptive/vaginal	vaginal		minor irritations	IIISE	withdraw	n/a
hemorrhoidal	anorectal		antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)
hemorrhoidal	anorectal		antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)
miscellaneous external	antifungal		diaper rash	defer	IISE	310.545(a)(22)(ii)
miscellaneous external	antimicrobial		diaper rash	defer	IISE	pending
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis		IISE	IISE	310.545(a)(7)
miscellaneous external	external analgesic		astringent	IISE	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external	skin protectant		diaper rash	defer	IIS	pending
oral cavity	oral health care		antimicrobial	IISE	IISE	pending
ophthalmic	ophthalmic		anti-infective	IIIIE	IIE	310.545(a)(21)(ii)
topical analgesic	skin protectant		skin protectant	IISE	IISE	310.545(a)(18)(i)(B)
bornelone						
topical analgesic	sunscreen		sunscreen	IIIIE	IIIIE	[64 FR 27682]

OTC Ingredient List
Updated May 2005

Ingredient Review Panel	Report	Drug Category	ANPR	PR	FR
bornyl acetate					
cough/cold	cough/cold (nasal decongestant)	nasal decongestant (topical)	IIIIE	IIIIE	310.545(a)(6)(ii)(B)
boroglycerin					
contraceptive/vaginal	vaginal	minor irritations	IIISE	withdraw n/a	
contraceptive/vaginal	vaginal	alters vaginal pH	IIISE	withdraw n/a	
contraceptive/vaginal	vaginal	astringent	IIISE	withdraw n/a	
contraceptive/vaginal	vaginal	lowers surface tension mucolytic effects	IIISE	withdraw n/a	
hemorrhoidal	anorectal	antiseptic (external)	IISE	IISE	310.545(a)(26)(ii)
hemorrhoidal	anorectal	antiseptic (intrarectal)	IISE	IISE	310.545(a)(26)(ii)
oral cavity	oral health care	antimicrobial	IISE	IISE	pending
boroglycerin glycerite [see boroglycerin]					
=====	=====	=====	=====	=====	=====
bran					
laxative	laxative	bulk laxative	I	I	pending
bran, dietary [see bran]					
=====	=====	=====	=====	=====	=====
bran, tablets [see bran]					
=====	=====	=====	=====	=====	=====

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
bromopheniramine maleate						
cough/cold		cough/cold (antihistamine)	antihistamine	I	I	341.12(a)
buchu						
miscellaneous internal	weight control		anorectic	I ^S E	I ^S E	310.545(a)(20)
buchu powdered extract (extract of buchu)						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	I ^S E	310.545(a)(24)(i)
buchu, extract						
miscellaneous internal	weight control		anorectic	I ^S E	I ^S E	310.545(a)(20)
buckthorn						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
buffered mixture anion/cation exchange resin [see anion/cation exchange resins]						
====	====	====	====	====	====	====
butacaine sulfate						
dental	relief of oral discomfort		oral mucosal analgesic	I	I	pending
dental	relief of oral discomfort		toothache relief	I ^S E	I ^S E	pending
butamben picrate						
====	external analgesic		fever blister (topical)	n/a	I	pending
====	external analgesic		poison ivy/oak/sumac	n/a	I	pending
topical analgesic	external analgesic		analgesic/anesthetic	I	I	pending

OTC Ingredient List
Updated May 2005

Ingredient			Drug Category	ANPR	PR	FR
Review Panel	Report					
butylated hydroxyanisole						
====	external analgesic		fever blister (topical)	n/a	n/a	pending
====	skin protectant		fever blister (topical)	n/a	n/a	pending
caffeine						
cough/cold	cough/cold (miscellaneous)		corrective	IIIE	IIIE	pending
internal analgesic	internal analgesic		analgesic adjuvant	IIIE	IIIE	pending
internal analgesic	internal analgesic		antipyretic adjuvant	IIIE	IIIE	pending
internal analgesic	internal analgesic		antirheumatic adjuvant	IIIE	n/a	pending
miscellaneous internal	menstrual/diuretic		analgesic adjuvant	IIIE	IIIE	pending
miscellaneous internal	menstrual/diuretic		diuretic	I	I	pending
miscellaneous internal	overindulgence in alcohol/food		overindulgence remedies (hangover)	I	I	pending
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
sedative	stimulant		stimulant	I	I	340.10
calamine						
hemorrhoidal	anorectal		astringent (external)	I	I	346.18(a)
hemorrhoidal	anorectal		astringent (intrarectal)	I	I	346.18(a)
hemorrhoidal	anorectal		protectant (intrarectal)	I	I	346.14(b)(1)
hemorrhoidal	anorectal		protectant (external)	I	I	346.14(b)(1)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
	miscellaneous external	external analgesic	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
	miscellaneous external	skin protectant	skin protectant	I	I	347.10(c)
	miscellaneous external	skin protectant	diaper rash	defer	I	pending
	miscellaneous external	skin protectant	insect bite/sting	IISE	IISE	310.545(a)(10)(vi)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	I	347.10(c)
	topical analgesic	skin protectant	skin protectant	I	I	347.10(c)
calamine (in combination only)						
hemorrhoidal		anorectal	protectant (intrarectal)	I	I	346.14(b)(1)
hemorrhoidal		anorectal	protectant (external)	I	I	346.14(b)(1)
calcium						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
calcium acetate						
====		skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
	miscellaneous external	external analgesic	astringent	IISE	n/a	pending
calcium carbaspirin [see carbaspirin calcium]						
====	====	====	====	====	====	====

OTC Ingredient List
Updated May 2005

Ingredient			Drug Category	ANPR	PR	FR
Review Panel	Report					
calcium carbonate						
	antacid	antacid	antacid	I	I	331.11(d)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
calcium carbonate, precipitated						
	laxative	antidiarrheal	antidiarrheal	IIIIE	IIIIE	310.545(a)(3)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending
calcium casinate						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
calcium gluconate						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
calcium hydroxide						
	laxative	antidiarrheal	antidiarrheal	IIIIE	IIIIE	310.545(a)(3)(ii)
calcium iodide, anhydrous						
cough/cold	cough/cold (expectorant)		expectorant	IISE	IISE	310.545(a)(6)(iii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
calcium lactate						
miscellaneous internal	menstrual/diuretic		diuretic	n/a	IISE	310.545(a)(24)(i)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
calcium pantothenate						
laxative	laxative		stimulant laxative	IIIIE	IIIIE	310.545(a)(12)(iv)(A)
miscellaneous external	wart remover		wart remover	IIIIE	IIIIE	[55 FR 33254]
miscellaneous internal	menstrual/diuretic		premenstrual/menstrual period	n/a	IISE	310.545(a)(24)(i)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
calcium phosphate						
antacid	antacid		antacid	I	I	331.11(d)
calcium phosphate, dibasic						
dental	anticaries		anticavity agent	IIIE	n/a	[60 FR 52504]
internal analgesic	internal analgesic		corrective	I	n/a	n/a
calcium phosphate, tribasic						
antacid	antacid		antacid	I	I	331.11(d)
calcium polysulfide						
antimicrobial II	acne		acne	IIIE	IIIE	310.545(a)(1)
calcium propionate						
contraceptive/vaginal	vaginal		minor irritations	I	withdraw	n/a

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
calcium salicylate						
internal analgesic	internal analgesic		analgesic	n/a	IISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antirheumatic	n/a	not OTC	310.545(a)(23)(i)
calcium salt (mono or dibasic)						
antacid	antacid		antacid	n/a	n/a	331.11(i)(2)
calcium silicate						
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	pending
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	pending
calcium sucrose phosphate						
dental	anticaries		anticavity agent	IIE	n/a	310.545(a)(2)(ii)
calcium thiosulfate						
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
calcium undecylenate						
antimicrobial II	antifungal		antifungal	I	I	333.210(f)
miscellaneous external	antifungal		diaper rash	defer	IISE	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	IIISE	pending
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis		dandruff/seborrheic dermatitis/psoriasis	IIISE	IIISE	310.545(a)(7)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
calomel						
laxative		laxative	stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
miscellaneous external		boil treatment	boil treatment	IISE	IISE	310.531(a)
miscellaneous external		mercury	antiseptic	IISE	IISE	310.545(a)(27)(i)
calomel (mercurous chloride)						
miscellaneous external		antimicrobial	first aid antiseptic	n/a	IIIIE	310.545(a)(27)(i)
calomel [see mercuric chloride]						
=====	=====	=====	=====	=====	=====	=====
camphor						
antimicrobial II		acne	acne	IIE	IIE	310.545(a)(1)
antimicrobial II		antifungal	antifungal	IIE	IIE	310.545(a)(22)(ii)
cough/cold		cold/cough (antitussive)	antitussive (topical/inhalant)	IIIIE	I	341.14(b)(1)
cough/cold		cough/cold (expectorant)	expectorant (lozenge)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold		cough/cold (expectorant)	expectorant (topical/inhalant)	IIIIE	IIIIE	310.545(a)(6)(iii)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (topical/inhalant)	IIIIE	IIIIE	[59 FR 43408]
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (lozenge)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)
dental		relief of oral discomfort	oral mucosal analgesic	IISE	IISE	pending
hemorrhoidal		anorectal	analgesic (external)	n/a	I	346.16(a)
miscellaneous external		antifungal	diaper rash	defer	IISE	310.545(a)(22)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	antimicrobial	diaper rash	defer	n/a	pending
	miscellaneous external	boil treatment	boil treatment	I	I	310.531(a)
	miscellaneous external	external analgesic	diaper rash	defer	I	310.545(a)(10)(iv)
	miscellaneous external	external analgesic	insect bite/sting	I	I	pending
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	I	pending
	miscellaneous external	skin protectant	diaper rash	defer	n/a	pending
	miscellaneous external	skin protectant	fever blister (topical)	defer	defer	pending
	miscellaneous external	skin protectant	insect bite/sting	I	I	310.545(a)(18)(v)(A)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	I	310.545(a)(10)(vii)(A)
	miscellaneous external	wart remover	wart remover	I	I	[55 FR 33254]
	miscellaneous external	external analgesic	external analgesic (less than 2.5%)	I	I	pending
	miscellaneous external	external analgesic	external analgesic (greater than 2.5%)	I	I	pending
oral cavity		oral health care	antimicrobial	I	I	pending
oral cavity		oral health care	analgesic/anesthetic	I	I	310.545(a)(14)
topical analgesic		external analgesic	counterirritant	I	I	pending
topical analgesic		external analgesic	analgesic/anesthetic	I	I	pending
topical analgesic		external analgesic	external analgesic	I	I	pending
topical analgesic		sunscreen	sunscreen	I	I	[64 FR 27682]
topical analgesic		external analgesic	antipyretic	n/a	I	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
camphor (>3 - 11 %)						
miscellaneous external	external analgesic		fever blister (topical)	defer	IISE	310.545(a)(10)(v)
camphor (0.1-3*%)						
miscellaneous external	external analgesic		fever blister (topical)	defer	I	pending
camphor (greater than 3% to 11%)						
hemorrhoidal	anorectal		counterirritant (intrarectal)	IISE	IISE	310.545(a)(26)(iv)
hemorrhoidal	anorectal		counterirritant (external)	IISE	IISE	310.545(a)(26)(iv)
camphor gum						
miscellaneous external	external analgesic		astringent	IISE	n/a	n/a
miscellaneous external	skin protectant		astringent	IISE	IISE	310.545(a)(18)(ii)
camphorated metacresol						
=====	external analgesic		fever blister (topical)	n/a	I	pending
=====	external analgesic		poison ivy/oak/sumac	n/a	I	pending
antimicrobial II	antifungal		antifungal	IIISE	IIISE	310.545(a)(22)(iv)
miscellaneous external	MALE GENITAL DESENSITIZER		male genital desensitizer	n/a	IISE	310.545(a)(10)(iii)
topical analgesic	external analgesic		analgesic/anesthetic	IIISE	I	pending
camphorated oil						
miscellaneous external	camphorated oil		counterirritant	IIS	n/a	310.502(a)(4)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
candelilla wax [see wax, candelilla]	=====	=====	=====	=====	=====	=====
candidin						
antimicrobial II	antifungal		anticandidial	I	I	310.545(a)(22)(ii)
cantharides						
miscellaneous internal	aphrodisiac		aphrodisiac	I	I	310.528(a)
capsaicin						
miscellaneous external	external analgesic		fever blister (topical)	defer	I	310.545(a)(10)(v)
topical analgesic	external analgesic		counterirritant	I	I	pending
capsicum						
dental	relief of oral discomfort		counterirritant (external)	III	III	pending
dental	relief of oral discomfort		toothache relief	I	I	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	I	310.545(a)(10)(v)
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(8)(ii)
topical analgesic	external analgesic		counterirritant	I	I	pending
capsicum oleoresin						
miscellaneous external	external analgesic		fever blister (topical)	defer	I	310.545(a)(10)(v)
miscellaneous internal	menstrual/diuretic		diuretic	n/a	I	310.545(a)(24)(i)
topical analgesic	external analgesic		counterirritant	I	I	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
capsicum, fluid extract of						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
captan						
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff		III	III	310.545(a)(7)
caramiphen edisylate						
cough/cold	cold/cough (antitussive)		antitussive	III	III	[52 FR 30054]
carbamide peroxide						
miscellaneous external	external analgesic		fever blister (topical)	defer	defer	pending
miscellaneous external	skin protectant		fever blister (topical)	defer	defer	pending
oral cavity	oral health care		debriding agent	III	III	pending
oral cavity	oral health care		antimicrobial	III	III	pending
carbamide peroxide (in anhydrous glycerin)						
dental	oral mucosal injury		wound cleanser	I	I	pending
dental	oral mucosal injury		wound healing agent	III	III	310.534(a)
carbamide peroxide 6.5% (in anhydrous glycerin)						
topical analgesic	otic		ear wax softening agent	I	I	344.10
carbaspirin calcium						
internal analgesic	internal analgesic		antipyretic	I	I	pending
internal analgesic	internal analgesic		analgesic	I	I	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	internal analgesic	internal analgesic	antirheumatic	I	not OTC	n/a
	miscellaneous internal	menstrual/diuretic	analgesic	I	I	pending
carbetapentane citrate						
cough/cold		cold/cough (antitussive)	antitussive	IIIIE	IIIIE	310.533(a)
carbon						
miscellaneous internal		digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
carbon dioxide, released						
laxative		laxative	laxative	I	I	pending
carboxymethylcellulose						
antacid		antacid	antacid	IIIIE	IIIIE	[39 FR 19874]
carboxymethylcellulose sodium						
laxative		antidiarrheal	antidiarrheal	IIIIE	IIIIE	310.545(a)(3)(i)
laxative		laxative	bulk laxative	I	I	pending
miscellaneous internal		weight control	anorectic	IIIIE	IISE	310.545(a)(20)
ophthalmic		ophthalmic	demulcent	I	I	349.12(a)(1)
carnauba wax [see wax, carnauba]						
=====	=====	=====	=====	=====	=====	=====
carrageenan						
miscellaneous internal		weight control	anorectic	IIIIE	IISE	310.545(a)(20)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
carrageenan (degraded) [see carrageenan, degraded]	=====	=====	=====	=====	=====	=====
carrageenan (native) [see carrageenan, native]	=====	=====	=====	=====	=====	=====
carrageenan, degraded						
laxative	laxative	bulk laxative		IIS	IIS	310.545(a)(12)(i)
carrageenan, native						
laxative	laxative	bulk laxative		IIIIE	IIIIE	310.545(a)(12)(i)
casanthranol						
laxative	laxative	stimulant laxative		I	I/IIIS	pending
cascara fluidextract aromatic [see cascara fluidextract, aromatic]	=====	=====	=====	=====	=====	=====
cascara fluidextract, aromatic						
laxative	laxative	stimulant laxative		I	I/IIIS	310.545(a)(12)(iv)(C)
miscellaneous internal	menstrual/diuretic	diuretic		n/a	IISE	310.545(a)(24)(i)
cascara sagrada						
laxative	laxative	stimulant laxative		I	I/IIIS	310.545(a)(12)(iv)(C)
cascara sagrada bark [see cascara sagrada]	=====	=====	=====	=====	=====	=====

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
cascara sagrada extract						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
cascarasagrada extract						
laxative	laxative		stimulant laxative	I	I/IIS	310.545(a)(12)(iv)(C)
cascarasagrada fluid extract						
laxative	laxative		stimulant laxative	I	I/IIS	310.545(a)(12)(iv)(C)
casein						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	n/a
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	withdraw n/a	
castor oil						
laxative	laxative		stimulant laxative	I	I	pending
miscellaneous external	external analgesic		fever blister (topical)	defer	n/a	n/a
miscellaneous external	skin protectant		fever blister (topical)	defer	n/a	n/a
miscellaneous external	wart remover		wart remover	IISE	IISE	[55 FR 33254]
catechu, tincture						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
catnip						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
cedar leaf oil						
cough/cold	cough/cold (nasal decongestant)		nasal decongestant (topical)	IIIIE	IIIIE	310.545(a)(6)(ii)(B)
cellulase						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(i)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIE	IIE	310.545(a)(8)(i)
cellulose						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	n/a
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	n/a	n/a
cellulose, microporous						
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	IIISE	pending
cetalkonium chloride						
miscellaneous external	external analgesic		poison ivy/oak/sumac	defer	IIISE	310.545(a)(10)(vii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(18)(vii)(A)
	oral cavity	oral health care	antimicrobial	IIIIE	IIIIE	pending
cetyl alcohol						
	=====	insect bite/sting	insect bite/sting	n/a	n/a	310.545(a)(18)(v)(B)
	=====	poison ivy/oak/sumac	poison ivy/oak/sumac	n/a	n/a	310.545(a)(18)(vi)(B)
	=====	skin protectant	skin protectant	n/a	n/a	310.545(a)(18)(i)(B)
	miscellaneous external	external analgesic	fever blister (topical)	n/a	n/a	n/a
	miscellaneous external	skin protectant	fever blister (topical)	defer	n/a	pending
cetylpyridinium chloride						
	=====	gingivitis/plaque	antiplague/gingivitis	n/a	I	pending
	oral cavity	oral health care	antimicrobial	IIISE	IIISE	pending
chamomile flowers						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
charcoal, activated						
	antacid	antacid	antacid	IIIIE	IIIIE	[39 FR 19873]
	laxative	antidiarrheal	antidiarrheal	IIIIE	IIIIE	310.545(a)(3)(ii)
	miscellaneous internal	deodorants for internal use	internal deodorant	IIIIE	IIIIE	[55 FR 19864]
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	IIIIE	IIIIE	310.545(a)(8)(iii)
	miscellaneous internal	overindulgence in alcohol/food	minimize hangover symptoms	IIIIE	IIIIE	[48 FR 32873]

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous internal	poison treatment	poison absorbent	n/a	I	pending
	miscellaneous internal	acute toxic ingestion	poison treatment	I	I	pending
charcoal, wood						
	miscellaneous internal	digestive aid	digestive aid (intestinal distress)	III	III	310.545(a)(18)(ii)
chlophedianol hydrochloride						
	cough/cold	cold/cough (antitussive)	antitussive	n/a	I	341.14(a)(1)
chloral hydrate						
	====	external analgesic	fever blister (topical)	n/a	II	310.545(a)(10)(v)
	miscellaneous external	external analgesic	poison ivy/oak/sumac	defer	II	310.545(a)(10)(vii)
	miscellaneous external	skin protectant	poison ivy/oak/sumac	defer	IIS	310.545(a)(10)(vii)(A)
	topical analgesic	external analgesic	analgesic/anesthetic	II	II	310.545(a)(10)(i)
	topical analgesic	external analgesic	counterirritant	n/a	n/a	310.545(a)(10)(ii)
chlorcyclizine hydrochloride						
	cough/cold	cough/cold (antihistamine)	antihistamine	n/a	I	341.12(b)
chlorhydroxyquinoline [see cloxyquin]						
	====	====	====	====	====	====
chlorobutanol						
	====	external analgesic	fever blister (topical)	n/a	II	310.545(a)(10)(v)
	====	external analgesic	poison ivy/oak/sumac	n/a	II	310.545(a)(10)(vii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous external	alcohols (topical)	antiseptic	IIE	defer	n/a
	miscellaneous external	corn/callus remover	corn/callus remover	IISE	IISE	[55 FR 33261]
	topical analgesic	external analgesic	analgesic/anesthetic	IIIIE	IIIIE	310.545(a)(10)(i)
chloroform						
cough/cold		cough/cold (expectorant)	expectorant	IISE	IISE	310.545(a)(6)(iii)
miscellaneous internal		digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
chlorophenothane						
miscellaneous external		pediculicide	pediculicide	IISE	IISE	310.545(a)(25)(i)
chlorophyll [see chlorophyllin copper complex]						
=====	=====	=====	=====	=====	=====	=====
chlorophyllin						
dental		relief of oral discomfort	oral mucosal analgesic	n/a	IIISE	pending
chlorophyllin copper complex						
dental		oral mucosal injury	wound healing agent	IIIIE	IIIIE	310.534(a)
miscellaneous internal		deodorants for internal use	internal deodorant	IIIIE	I	357.810(b)
oral cavity		oral health care	antimicrobial	IIIIE	IIIIE	pending
chlorophyllins, water-soluble [see chlorophyllin copper complex]						
=====	=====	=====	=====	=====	=====	=====

OTC Ingredient List
Updated May 2005

Ingredient			Drug Category	ANPR	PR	FR
Review Panel	Report					
chlorothymol						
antimicrobial II	antifungal		antifungal	IIISE	IIISE	310.545(a)(22)(ii)
chloroxyneol						
antimicrobial I	antimicrobial		first aid antiseptic	n/a	IIIIE	pending
antimicrobial I	antimicrobial		antimicrobial soap	IIISE	IIISE	pending
antimicrobial I	antimicrobial		preoperative skin prep	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin wound cleanser	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin wound protectant	IIISE	IIISE	pending
antimicrobial I	antimicrobial		skin antiseptic	IIISE	IIISE	pending
antimicrobial I	antimicrobial		surgical hand scrub	IIISE	IIISE	pending
antimicrobial I	antimicrobial		health care personnel handwash	IIIIE	IIIIE	pending
antimicrobial II	acne		acne	IIE	IIE	310.545(a)(1)
antimicrobial II	antifungal		antifungal	IIIIE	IIIIE	310.545(a)(22)(iv)
miscellaneous external	antifungal		diaper rash	defer	IIISE	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	IIISE	pending
miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff/seborrheic dermatitis		IIISE	IIISE	310.545(a)(7)
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	ingrown toenail		ingrown toenail	IISE	IISE	310.538(a)
miscellaneous external	skin protectant		diaper rash	defer	n/a	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
chlorpheniramine maleate						
cough/cold		cough/cold (antihistamine)	antihistamine	I	I	341.12(c)
miscellaneous external		external analgesic	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)
miscellaneous external		skin protectant	poison ivy/oak/sumac	defer	IISE	310.545(a)(10)(vii)(A)
chlorphenpropyridamine maleate						
miscellaneous internal		menstrual/diuretic	menstrual	n/a	IISE	310.545(a)(24)(i)
chlortetracycline hydrochloride						
antimicrobial II		antibiotic	first aid antibiotic	n/a	I	333.110(c)
antimicrobial II		antibiotic	skin wound antibiotic	IIE	defer	n/a
antimicrobial II		antibiotic	skin wound protectant	I	defer	n/a
chloxyquin						
antimicrobial II		acne	acne	IISE	IISE	310.545(a)(1)
cholecalciferol						
hemorrhoidal		anorectal	wound healing agent (external)	IIIE	IIIE	310.545(a)(26)(x)
hemorrhoidal		anorectal	wound healing agent (intrarectal)	IIIE	IIIE	310.545(a)(26)(x)
miscellaneous external		antifungal	diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external		antimicrobial	diaper rash	defer	n/a	Pending
miscellaneous external		external analgesic	diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external		skin protectant	diaper rash	defer	IISE	Pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
cholesterol						
	miscellaneous external	boil treatment	boil treatment	IISE	IISE	310.531(a)
choline						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)
choline salicylate						
internal analgesic	internal analgesic	analgesic	I	I	pending	
internal analgesic	internal analgesic	antipyretic	I	I	pending	
internal analgesic	internal analgesic	antirheumatic	I	not OTC	n/a	
miscellaneous internal	menstrual/diuretic	analgesic	I	I	pending	
chondrus						
	miscellaneous internal	weight control	anorectic	IIIIE	IISE	310.545(a)(20)
cimicifuga racemosa						
	miscellaneous internal	menstrual/diuretic	dysmenorrhea	IISE	IISE	310.545(a)(24)(i)
cinnamedrine hydrochloride						
	miscellaneous internal	menstrual/diuretic	smooth muscle relaxant	IIIIE	IIIIE	pending
cinnamon oil						
	miscellaneous internal	digestive aid	digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
cinnamon tincture						
miscellaneous internal	digestive aid		digestive aid (ippuad)	n/a	n/a	310.545(a)(18)(ii)
cinoxate						
topical analgesic	sunscreen		sunscreen	I	I	352.10(c)
citric acid						
contraceptive/vaginal	vaginal		alters vaginal pH	IIIIE	withdraw	n/a
dental	relief of oral discomfort		tooth desensitizer (in combination only)	IIIIE	IIIIE	pending
internal analgesic	internal analgesic		corrective	I	n/a	n/a
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	IIIIE	n/a	310.545(a)(18)(ii)
miscellaneous internal	digestive aid		digestive aid (ippuad)	IIIIE	n/a	310.545(a)(18)(ii)
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
citric acid/salt						
antacid	antacid		antacid	I	I	331.11(e)
citrus pectin						
miscellaneous internal	digestive aid		digestive aid (intestinal distress)	n/a	n/a	310.545(a)(18)(ii)
clioquinol						
antimicrobial II	antifungal		antifungal	I	I	333.210(a)
clofucarban						
antimicrobial I	antimicrobial		skin antiseptic	n/a	IISE	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
	antimicrobial I	antimicrobial	skin wound protectant	IISE	IISE	pending
	antimicrobial I	antimicrobial	first aid antiseptic	IISE	IISE	pending
	antimicrobial I	antimicrobial	antimicrobial soap	IIIS	IIIS	pending
	antimicrobial I	antimicrobial	skin wound cleanser	IISE	IIISE	pending
	antimicrobial I	antimicrobial	preoperative skin prep	IISE	IISE	pending
	antimicrobial I	antimicrobial	surgical hand scrub	IISE	IISE	pending
	antimicrobial I	antimicrobial	health care personnel handwash	IIISE	IIISE	pending
clotrimazole						
	n/a	n/a	antifungal	n/a	I	[67 FR 5942]
clove						
	miscellaneous internal	smoking deterrent	smoking deterrent	IIE	IIE	310.544(d)
clove oil						
	miscellaneous external	external analgesic	astringent	IISE	n/a	pending
	miscellaneous external	skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
cloves, ground [see clove]						
	====	====	====	====	====	====
cnicus benedictus						
	miscellaneous internal	weight control	anorectic	IISE	IISE	310.545(a)(20)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
coal tar						
	antimicrobial II	acne	acne	I	I	IISE 310.545(a)(1)
	antimicrobial II	antifungal	antifungal	I	I	IISE 310.545(a)(22)(ii)
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	psoriasis			358.710(c)(1)
coal tar (shampoo)						
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	dandruff	I	I	358.710(a)(1)
coal tar (non shampoo)						
	miscellaneous external	dandruff/seborrheic dermatitis/psoriasis	seborrheic dermatitis	III	I	358.710(b)(1)
cocoa butter						
	=====	skin protectant	diaper rash	defer	IISE	310.545(a)(18)(iii)
	=====	skin protectant	fever blister (topical)	n/a	I	pending
	hemorrhoidal	anorectal	protectant (external)	I	I	346.14(2)
	hemorrhoidal	anorectal	protectant (intrarectal)	I	I	346.14(2)
	topical analgesic	skin protectant	skin protectant	I	I	347.10(d)
cocoa butter substitutes [see hard fat]						
	=====	=====	=====	=====	=====	=====
coconut oil soap, aqueous						
	miscellaneous external	pediculicide	pediculicide	II	II	310.545(a)(25)(i)

OTC Ingredient List
Updated May 2005

Ingredient			Drug Category	ANPR	PR	FR
Review Panel	Report					
cod liver oil						
=====	skin protectant		skin protectant	n/a	n/a	347.10(e)
cough/cold	cold/cough (antitussive)		antitussive	IIIIE	IIIIE	[52 FR 30054]
hemorrhoidal	anorectal		wound healing agent (intrarectal)	IIISE	IIISE	310.545(a)(26)(x)
hemorrhoidal	anorectal		wound healing agent (external)	IIISE	IIISE	310.545(a)(26)(x)
miscellaneous external	antifungal		diaper rash	defer	n/a	310.545(a)(22)(i)
miscellaneous external	antimicrobial		diaper rash	defer	n/a	pending
miscellaneous external	external analgesic		diaper rash	defer	n/a	310.545(a)(10)(iv)
miscellaneous external	skin protectant		diaper rash	defer	I	pending
cod liver oil (in combination only)						
hemorrhoidal	anorectal		protectant (external)	I	I	346.14(b)(2)
hemorrhoidal	anorectal		protectant (intrarectal)	I	I	346.14(b)(2)
codeine						
=====	menstrual/diuretic		menstrual	n/a	n/a	310.545(a)(24)(i)
cough/cold	cold/cough (antitussive)		antitussive	I	I	341.14(a)(2)(i)
internal analgesic	internal analgesic		analgesic	IIISE	IIISE	310.545(a)(23)(i)
internal analgesic	internal analgesic		antipyretic	IIISE	IIISE	310.545(a)(23)(i)
miscellaneous internal	menstrual/diuretic		analgesic	IIS	IISE	310.545(a)(24)(i)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
codeine phosphate						
cough/cold		cold/cough (antitussive)	antitussive	I	I	341.14(a)(2)(ii)
internal analgesic		internal analgesic	analgesic	IISE	n/a	310.545(a)(23)(i)
codeine sulfate						
cough/cold		cold/cough (antitussive)	antitussive	I	I	341.14(a)(2)(iii)
internal analgesic		internal analgesic	analgesic	IISE	n/a	310.545(a)(23)(i)
codeine, alkaloid [see codeine]						
=====	=====	=====	=====	=====	=====	=====
collinsonia extract						
hemorrhoidal		anorectal	anorectal (external)	IISE	IISE	310.545(a)(26)(vii)
hemorrhoidal		anorectal	anorectal (intrarectal)	IISE	IISE	310.545(a)(26)(vii)
miscellaneous internal		menstrual/diuretic	diuretic	n/a	IISE	310.545(a)(24)(i)
colloidal oatmeal						
=====		skin protectant	skin protectant	n/a	n/a	347.10(f)
=====		skin protectant	poison ivy/oak/sumac	n/a	I	347.10(f)
miscellaneous external		dandruff/seborrheic dermatitis/psoriasis	dandruff	IIE	IIE	310.545(a)(7)
miscellaneous external		external analgesic	astringent	IISE	n/a	pending
miscellaneous external		skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous external		skin protectant	diaper rash	defer	IISE	pending

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
colocynth						
laxative	laxative		stimulant laxative	IIS	IIS	310.545(a)(12)(iv)(A)
				====	====	====
compound white pine syrup [see white pine syrup, compound]						
====	====		====	====	====	====
copper						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
copper gluconate						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)
copper oleate						
miscellaneous external	pediculicide		pediculicide	IISE	IISE	310.545(a)(25)(i)
copper undecylenate						
antimicrobial II	antifungal		antifungal	I	I	333.210(f)
coriander						
miscellaneous internal	smoking deterrent		smoking deterrent	IIE	IIE	310.544(d)
coriander, ground [see coriander]						
====	====		====	====	====	====
corn oil						
miscellaneous internal	weight control		anorectic	IISE	IISE	310.545(a)(20)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
corn oil, aqueous emulsion						
miscellaneous internal	cholecystokinetic	cholecystokinetic		I	I	357.210(a)
corn silk						
miscellaneous internal	menstrual/diuretic	diuretic		n/a	IISE	310.545(a)(24)(i)
corn silk, potassium extract						
miscellaneous internal	weight control	anorectic		IISE	IISE	310.545(a)(20)
corn starch [see starch, corn]						
=====	=====	=====		=====	=====	=====
corn syrup						
miscellaneous internal	weight control	anorectic		IISE	IISE	310.545(a)(20)
couch grass						
miscellaneous internal	menstrual/diuretic	diuretic		n/a	IISE	310.545(a)(24)(i)
creosote						
dental	relief of oral discomfort	toothache relief		IIIE	IIIE	pending
miscellaneous external	skin protectant	poison ivy/oak/sumac		defer	IISE	310.545(a)(10)(vii)(A)
creosote, beechwood						
=====	skin protectant	poison ivy/oak/sumac		n/a	IISE	310.545(a)(18)(vi)
cough/cold	cold/cough (antitussive)	antitussive		IIIE	IIIE	[52 FR 30054]
cough/cold	cough/cold (expectorant)	expectorant		IIIE	IIIE	310.545(a)(6)(iii)

OTC Ingredient List
Updated May 2005

Ingredient			Drug Category	ANPR	PR	FR
	Review Panel	Report				
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (oral)	IIIIE	IIIIE	310.545(a)(6)(ii)(A)
cough/cold		cough/cold (nasal decongestant)	nasal decongestant (topical)	IIIIE	IIIIE	310.545(a)(6)(ii)(B)
dental		relief of oral discomfort	toothache relief	IIISE	IIISE	pending
miscellaneous external		external analgesic	poison ivy/oak/sumac	defer	IIISE	310.545(a)(10)(vii)
cresol						
antimicrobial II		antifungal	antifungal	IIISE	IIISE	310.545(a)(22)(iv)
dental		relief of oral discomfort	toothache relief	IIISE	IIISE	pending
miscellaneous external		external analgesic	astringent	IISE	n/a	pending
miscellaneous external		astringent	antiseptic	IIE	defer	n/a
miscellaneous external		skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
oral cavity		oral health care	antimicrobial	IIS	IISE	pending
oral cavity		oral health care	analgesic/anesthetic	IISE	IISE	310.545(a)(14)
oral cavity		relief of oral discomfort	oral mucosal analgesic	IIISE	IISE	pending
cresol saponated						
miscellaneous external		dandruff/seborrheic dermatitis/psoriasis	psoriasis	IIE	IIE	310.545(a)(7)
cupric sulfate						
miscellaneous external		external analgesic	astringent	IISE	n/a	pending
miscellaneous external		skin protectant	astringent	IISE	IISE	310.545(a)(18)(ii)
miscellaneous internal		weight control	anorectic	IISE	IISE	310.545(a)(20)

OTC Ingredient List
Updated May 2005

Ingredient	Review Panel	Report	Drug Category	ANPR	PR	FR
cyanocobalamin (vitamin B12)						
miscellaneous internal	weight control		anorectic		IISE	IISE
						310.545(a)(20)
cyclizine hydrochloride						
laxative	antiemetic		antiemetic		I	I
						336.10(a)
cyclomethycaine sulfate						
=====	external analgesic		fever blister (topical)		n/a	IIIIE
=====	external analgesic		poison ivy/oak/sumac		n/a	IIIIE
internal analgesic	external analgesic		analgesic/anesthetic		IIIIE	IIIIE
						310.545(a)(10)(i)
cysteine hydrochloride						
miscellaneous external	antifungal		diaper rash		defer	n/a
miscellaneous external	antimicrobial		diaper rash		defer	n/a
miscellaneous external	external analgesic		diaper rash		defer	n/a
miscellaneous external	skin protectant		diaper rash		defer	IIISE
						310.545(a)(18)(iii)
cystine						
miscellaneous internal	weight control		anorectic		IISE	IISE
						310.545(a)(20)